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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,464	08/25/2003	James D. Ralph	F-286 SPING 30-446 CIP/111 COM	8288
51640	7590	06/01/2005	EXAMINER	
LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK, LLP 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			BLANCO, JAVIER G	
			ART UNIT	PAPER NUMBER
			3738	

FINAL DUE
01 SE 2005

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

JUN 03 2005

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Office Action Summary

Application No.

10/648,464

Applicant(s)

RALPH ET AL

Examiner

Javier G. Blanco

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,7-9,11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,7-9,11 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/28/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicants' cancellation of claims 4, 6, and 10 in the reply filed on February 28, 2005 is acknowledged.
2. Applicants' amendment of independent claims 1 and 7 in the reply filed on February 28, 2005 is acknowledged.

Terminal Disclaimer

3. The terminal disclaimer filed on February 28, 2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 6,764,515 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Objections

4. Claims 11 and 12 are objected to because of the following informalities:
 - a. Regarding claim 11, please add --deflectable-- in front of "convex" (see line 2). This is to conform to recently amended independent claim 7. Appropriate correction is required.
 - b. Regarding claim 12, please add --deflectable-- in front of "convex" (see line 2). This is to conform to recently amended independent claim 7. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3738

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 5, 7, 11, and 12 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Stubstad et al. (US 3,867,728 A; cited in Applicants' IDS).

Referring to Figures 1, 2, and 4, Stubstad et al. disclose an intervertebral spacer device (device 10) comprising: (i) first (top element 11) and second (bottom element 12) plate members, each having an external plate surface *adapted to seat* (emphasis added to functional language) against an opposing bone surface, the plate members being disposed such that the external plate surfaces face in opposite directions, at least one of the external plate surfaces having a deflectable/deformable (see column 8, lines 46-49; column 9, lines 14-17), convex (see Figure 4; see column 13, lines 24-26), wire mesh (e.g., Dacron mesh 21 and/or Dacron mesh 20; see column 8, lines 6-10 and lines 43-59; column 9, lines 10-18) thereon, wherein the deflectable convex wire mesh is capable of deforming *for seating* (emphasis added to functional language) against one of the opposing bone surfaces (see entire document).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3738

8. Claims 1-3, 5, 7-9, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ralph et al. (US 5,989,291; previously cited in PTO-892) in view of Stubstad et al. (US 3,867,728 A; cited in Applicants' IDS).

As seen in Figures 3b, 4, 5, and 7-9, Ralph et al. disclose an intervertebral spacer device comprising first and second plate members (e.g., 100a, 100b), each having an external plate surface (e.g., 102a, 102b) thereof, the plate members being disposed such that the external plate surfaces face in opposite directions. Ralph et al. disclose plate members 100a, 100b as convex (see column 2, lines 61-63) and as having a porous coating (see column 3, lines 4-6; column 5, lines 57-61). Additionally, Ralph et al. teach a porous, resilient/flexible (i.e., deflectable; see column 3, lines 8-18; column 6, lines 17-21), and convex (see Figures 4 and 9) fabric/mesh (circumferential wall 120) on an external lateral portion of the intervertebral spacer device (see Figures 4, 6, and 9). Further, Ralph et al. disclose ball-shaped head 207 to be received and hold within curvate volume 233 (see columns 6 and 7).

Although Ralph et al. disclose the external plate surfaces as convex to match the contour of the opposing bone surface (see column 2, lines 61-65), and a porous coating on said external plate surfaces to provide for tissue ingrowth (see column 3, lines 4-6; column 5, lines 57-61), they did not particularly disclose said external plate surfaces as having a deflectable/deformable surface (or mesh) thereon. However, this is well known in the art. For example, Stubstad et al. teach an intervertebral spacer device comprising external plate surfaces having a deflectable/deformable, convex wire mesh thereon (see 102(b) rejection above) in order for the external plate surfaces to adapt/match to any small irregularities in the vertebral surfaces and to enable deeper tissue ingrowth on said external plate surfaces (see columns 8 and 9).

Art Unit: 3738

Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of an intervertebral spacer device comprising external plate surfaces having a deflectable/deformable, convex wire mesh thereon, as taught by Stubstad et al., with the intervertebral spacer device of Ralph et al., in order for the external plate surfaces to adapt/match to any small irregularities in the vertebral surfaces and to enable deeper tissue ingrowth on said external plate surfaces.

Response to Arguments

9. Applicant's arguments with respect to claims 1 and 7 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 3738

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

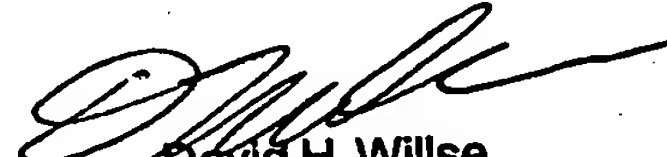
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB



May 24, 2005



David H. Willse
Primary Examiner



PTO/SB/08a/b (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE


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Substitute for form 1449A/B/PTO		Complete If Known	
		Application Number	10/648,464
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Filing Date	August 25, 2003
		First Named Inventor	James D. Ralph
		Art Unit	3738
		Examiner Name	J. G. Blanco
		Attorney Docket Number	SPINE 3.0-446 CIP III CONT
Sheet	1	of	3

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number+Kind Code ² (If known)			
JP	AA	US-2001/0016773-A1	08-23-2001	Serhan et al.	
	AB	US-2002/0111681-A1	05-25-2004	Ralph et al.	
	AC	US-2002/0111682-A1	08-15-2002	Ralph et al.	
	AD	US-2002/0111683-A1	12-30-2003	Ralph et al.	
	AE	US-2002/0111684-A1	08-15-2002	Ralph et al.	
	AF	US-2002/0111685-A1	08-15-2002	Ralph et al.	
	AG	US-2002/0111686-A1	07-20-2004	Ralph et al.	
	AH	US-2002/0111687	08-15-2002	Ralph et al.	
	AI	US-2002/0128714-A1	09-12-2002	Manasas et al.	
	AJ	US-2002/0143399-A1	10-19-2004	Sutcliffe	
	AK	US-2003/0009223-A1	08-03-2004	Fehling et al.	
	AL	US-2003/0009224-A1	08-19-2003	Kuras	
	AM	US-2003/0014110-A1	10-19-2004	Ralph et al.	
	AN	US-2003/0014111-A1	03-04-2003	Ralph et al.	
	AO	US-2003/0014112-A1	04-20-2004	Ralph et al.	
	AP	US-2003/0040801-A1	07-06-2004	Ralph et al.	
	AQ	US-2003/0045939-A1	11-11-2003	Casutt	
	AR	US-2003/0069586-A1	04-10-2003	Errico et al.	
	AS	US-2003/0069642-A1	04-10-2003	Ralph et al.	
	AT	US-2003/0074067-A1	04-17-2003	Errico et al.	
	AU	US-2003/0078662-A1	01-06-2004	Ralph et al.	
	AV	US-2003/0078663-A1	12-30-2003	Ralph et al.	
	AW	US-2003/0078664	04-24-2003	Ralph et al.	
	AX	US-2003/0078665-A1	11-11-2003	Ralph et al.	
	AY	US-2003/0078666-A1	08-26-2003	Ralph et al.	
	AZ	US-2003/0078667-A1	10-12-2004	Manasas et al.	
	AA1	US-2003/0083749-A1	05-01-2003	Kuslich et al.	
	AB1	US-2003/0191534-A1	01-27-2004	Viat et al.	
	AC1	US-2003/0199981-A1	03-16-2004	Ferree	
	AD1	US-2003/0204260-A1	10-30-2003	Ferree	
	AE1	US-2003/0208271-A1	11-06-2003	Kuras	
	AF1	US-2003/0233097-A1	12-18-2003	Ferree	
	AG1	US-2003/0233148-A1	12-18-2003	Ferree	
	AH1	US-2004/0002759-A1	01-01-2004	Ferree	
	AI1	US-2004/0002761-A1	01-01-2004	Rogers et al.	
	AJ1	US-2004/0002762-A1	09-21-2004	Hawkins	
	AK1	US-2004/0010316-A1	01-15-2004	William et al.	
	AL1	US-2004/0030390-A1	02-12-2004	Ferree	
	AM1	US-2004/0030391-A1	02-12-2004	Ferree	
	AN1	US-3,867,728			
	AO1	US-4,309,777	01-12-1982	Patil	
	AP1	US-4,759,766	07-26-1988	Buettner-Janz et al.	
	AQ1	US-4,759,769	07/1988	Hedman et al.	
	AR1	US-5,002,576	03-26-1991	Fuhrmann et al.	
	AS1	US-5,122,130	06-16-1992	Keller	
AT1	US-5,258,031	11-02-1993	Saito et al.		
Examiner Signature	James S. Blanco			Date Considered	May 25, 2005

Substitute for form 1449A/B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	10/648,464
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				Art Unit	3738
				Examiner Name	J. G. Blanco
Sheet	2	of	3	Attorney Docket Number	SPINE 3.0-446 CIP III CONT

22	AU1	US-5,314,477	05-24-1994	Mamay	
	AV1	US-5,370,697	12-06-1994	Baumgartner	
	AW1	US-5,401,269	03-28-1995	Buttner-Janz et al.	
	AX1	US-5,425,773	06/1995	BOYD ET AL	
	AY1	US-5,458,642	10/1995	Beer et al.	
	AZ1	US-5,507,816	04-16-1996	Bullivant	
	AA2	US-5,556,431	09/1996	Buttner-Janz	
	AB2	US-5,562,738	10/1996	Boyd et al.	
	AC2	US-5,674,298	10/1997	Bryan et al.	
	AD2	US-5,676,701	10/1997		
	AE2	US-5,683,465	11/1997	Shinn et al.	
	AF2	US-5,755,796	05/1998	Ibo et al.	
	AG2	US-5,782,832	07-21-1998	Larsen et al.	
	AH2	US-5,865,846	02/1999	Bryan et al.	
	AI2	US-5,888,226	03/1999	Rogozinski	
	AJ2	US-5,893,889	04/1999	Harrington	
	AK2	US-5,895,428	04/1999	Berry	
	AL2	US-5,899,941	05/1999	Nishijima et al.	
	AM2	US-5,928,284	07-27-1999	Mehdizadeh	
	AN2	US-5,989,291	11/1999	Ralph et al.	
	AO2	US-6,001,130	12/1999	Bryan et al.	
	AP2	US-6,146,421	11/2000	Gordon et al.	
	AQ2	US-6,156,087	12/2000	Bryan et al.	
	AR2	US-6,228,118	05/2001	Gordon	
	AS2	US-6,296,665	10/2001	Strnad et al.	
	AT2	US-6,368,350	04/2002	Erickson et al.	
	AU2	US-6,375,682	04-23-2002	Fleischmann et al.	
	AV2	US-6,416,551	07-09-2002	Keller	
	AW2	US-6,468,310	10/2002	Ralph et al.	
	AX2	US-6,517,580	02-11-2003	Ramadan et al.	
	AY2	US-6,520,996	02/2003	Manasas et al.	
	AZ2	US-6,527,804	03-04-2003	Gauchet et al.	
	AA3	US-6,527,806-A1	03-04-2003	Ralph et al.	
	AB3	US-6,540,785	04-01-2003	Gill et al.	
	AC3	US-6,579,320	06-17-2003	Gauchet et al.	
	AD3	US-6,582,466	06-24-2003	Gauchet	
	AE3	US-6,582,468	06-24-2003	Gauchet	
	AF3	US-6,592,624	07-15-2003	Fraser et al.	
	AG3	US-6,607,558-A1	08-19-2003	Kuras	
	AH3	US-6,610,092	08-26-2003	Ralph et al.	
	AI3	US-6,645,248-A1	11-11-2003	Casutt	
	AJ3	US-6,645,249-B2	11/2003	RALPH ET AL.	
	AK3	US-6,669,730	12-30-2003	Ralph et al.	
	AL3	US-6,669,731	12-30-2003	Ralph et al.	
	AM3	US-6,669,732-A1	12-30-2003	Serhan et al.	
	AN3	US-6,673,113-A1	01-06-2004	Ralph et al.	
	AO3	US-6,682,562	01-27-2004	Viat et al.	

Examiner Signature 546806		Date Considered	May 25, 2005
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Sheet	3	of	3	Attorney Docket Number	SPINE 3.0-446 CIP III CONT

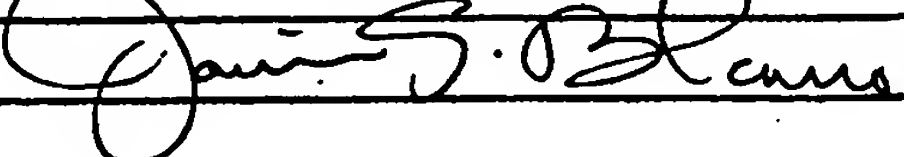
FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ²
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				

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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²

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¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	May 25, 2005
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